

## **Remarks**

### **I. Interview Summary**

Applicants wish to thank the Examiner for considering the issues raised in the April 21, 2008 Office Action during the interview on July 15, 2008.

During the interview, the Examiner and Applicants' attorneys discussed the cited prior art and claim amendments that would distinguish the prior art. The claim amendments discussed in the interview are reflected above. The remainder of the substance of the interview is further reflected below.

Applicants believe the application is now in a condition for allowance and appreciate the Examiner's due consideration of the amendments above and the following comments.

### **II. Introduction**

Claims 1-22 are pending in the application, including independent claims 1, 19, and 20. In the Office Action dated April 21, 2008, claims 1, 2, 5, 9, 12-16, and 21 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,122,136 ("Guglielmi"). Claims 6, 7, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. Guglielmi. Claims 3, 4, 8, 10, 11, 19, and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Guglielmi in view of U.S. Pat. No. 5,669,931 ("Kupiecki"). Finally, claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Guglielmi in view of U.S. Pat. No. 4,994,069 ("Ritchart").

Applicants have carefully considered the Examiner's comments. In order to expedite prosecution of Applicants' claims, claims 1, 3, 4, 8, 10, 11, 19, and 20 have been amended. Applicants respectfully request reconsideration and withdrawal of the rejections in light of the amendments to the claims and the following remarks.

### **III. Rejections under 35 USC § 112**

Claims 1-22 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Per the Examiner's suggestion during the interview of July 15, Applicants have amended independent claims 1, 3, 4, 8, 10, 11, 19, and 20 to recite a wire body that is substantially straight in a "predetermined unloaded shape." The term "predetermined unloaded shape" is meant to define a state in which the wire body has no load or stress applied thereto, and is recited in at least paragraphs [0022], [0023], [0029], and [0030] of the specification.

Further, in response to the Examiner's rejection of claim 1 and 19, Applicants have deleted the language "without a change in temperature of said wire body" from claims 1 and 19. Applicants note that during the interview of July 15, the Examiner stated that the removal of this language would not raise new issues with respect to the prior art. Applicants respectfully submit that the claims as amended comply with the written description requirement, and the Examiner may withdraw of the rejection.

### **IV. Guglielmi Does Not Anticipate Claim 1**

Independent claim 1 was rejected as being anticipated by Guglielmi. As amended, claim 1 recites with underlining for emphasis:

abutting a first wall portion of said blood vessel area with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion;

continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of said wire body toward a second wall portion of said blood vessel area, wherein said section of said wire body frictionally locks against said second wall portion of said blood vessel area when said section is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said blood vessel area that is frictionally locked to said first wall portion and said second wall portion due to said column loading;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said blood vessel area to be occluded using said section of said wire body frictionally locked between said first and second wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and said catheter is removed from said blood vessel area to be occluded; and

forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and said catheter is removed from said blood vessel area to be occluded.

Guglielmi fails to disclose at least these elements. As discussed during the interview of July 15, Guglielmi discloses three different embodiments for performing endovascular electrothrombosis. Col. 2, ll. 19-27; Col. 4, ll. 1-14, 36-62. As shown in Figs. 1 and 1A, the first embodiment includes a secondary coil 28 that is prebiased to form a cylindrical or conical spiral or a helix. The prebiased spiral 28 is connected to a stainless steel coil 26. Col. 6, ll. 18-47. In operation, the spirally shaped secondary coil 28 is placed into an aneurysm and a current is applied to a guidewire from an external voltage source, which causes the spirally shaped coil 28 to be positively charged. Col. 6, ll. 48-55. The positively charged coil (electrode) attracts negatively charged white blood cells, red blood cells, platelets, and fibrinogen, thereby causing a thrombic mass to form about the spirally shaped coil 28. *Id.*; Col. 2, ll. 19-27. Once the thrombic mass is formed, the secondary coil is detached from the stainless steel coil 26 by continuing to apply current while a portion 18 of the stainless steel coil 26 is exposed to blood, thereby causing a portion of the stainless steel coil 26 to disintegrate. Col. 6, ll. 55-62. Upon detaching the secondary coil 28, the guidewire is withdrawn, leaving the secondary coil 28 embedded within the thrombus formed within the aneurysm. Col. 6, ll. 62-65.

As shown in Figs. 2, 2A, the second embodiment includes a short wire body that is straight, but as described in the specification, this wire body does not include a bonding location (e.g., 22, 52 of Figures 1 and 3) for separating the wire body from the guidewire. (Col. 6, line 66 to col. 7, line 11). Thus, Figure 2 does not disclose a wire body that is released into the aneurysm and is frictionally locked to opposing walls of the aneurysm.

The third embodiment is shown in Figs. 3-5. The third embodiment includes a free and open platinum coil 56 made of a platinum alloy that is "particularly pliable" and that is "distinguished by its length of 1 to 50 cm and by its flexibility." As shown in Figs. 4-5, the flexible platinum coil 56 is fed into an aneurysm, and due to its pliable and flexible nature, the coil assumes an irregular free-form configuration. Once the coil is located within the aneurysm, a positive electric current is applied to the platinum coil 56 to form a thrombic mass about the platinum coil 56. Col. 8, ll. 5-15. Next, "[a]fter the thrombus has been formed and the aneurysm completely occluded, tip 58 and the coil 56 are detached from guidewire 42 by electro disintegration of at least one portion of stainless steel coil 46." Col. 8, ll. 15-19. Thus, Guglielmi merely discloses the endovascular use of a prebiased or very pliable and flexible electrode that occludes blood flow by forming a thrombus about the electrode using electrothrombosis.

Amended claim 1 recites occluding blood flow in a blood vessel area to be occluded using a wire body that is frictionally locked between first and second wall portions of an aneurysm by column loading. Guglielmi fails to disclose, and in fact teaches away from this step. As discussed above, Guglielmi discloses a platinum coil that is defined by its flexibility and pliability. As shown in Figs. 4-5, the flexible platinum coil is then fed into an aneurysm and assumes a free-form shape. Because the platinum coil is so flexible and pliable, as the coil is fed into the aneurysm and contacts the wall of the aneurysm, the coil simply crumples under the compressive force. Figs. 4-5. Thus, the flexible and pliable platinum coil disclosed in Guglielmi is not

capable of frictionally locking between a first and second wall portion of the blood vessel area to be occluded by column loading, as recited in amended claim 1.

Guglielmi also fails to disclose, and actually teaches away from occluding blood flow using the section of the wire body frictionally locked between the first and second wall portions of the blood vessel area. As discussed above, Guglielmi discloses occluding blood flow by forming a thrombus around the coil via electrothrombosis. Thus, the coil disclosed in Guglielmi and the wire body recited in amended claim 1 serve entirely different purposes. The coil disclosed in Guglielmi is merely an electrode that serves to form a thrombus via electrothrombosis; that is, the coil is not an occluding device itself. In contrast, the wire body recited in amended claim 1 actually is the occluding device.

In fact, as described above, the flexible, pliable platinum coil taught by Guglielmi does not have sufficient structural rigidity to frictionally lock against a first wall portion, and then frictionally lock against a second wall portion when the wire body is column loaded. Indeed, changing the flexible pliable platinum coil to a wire having sufficient structural rigidity to frictionally lock against a vessel wall under column loads, as recited in amended claim 1, would change the principle operation of Guglielmi. See MPEP § 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."). The principle operation of the flexible platinum coil (or secondary coil) of Guglielmi is to provide an electrode that can crumple into an aneurysm and occlude blood flow through electrothrombosis. Thus, it would not be obvious to modify the flexible, pliable electrode of Guglielmi to frictionally lock to sides of the blood vessel wall and occlude blood flow using the wire itself.

Furthermore, Guglielmi fails to disclose, and actually teaches away from occluding blood flow and forming a thrombus after the wire body is separated from the catheter and the catheter is removed from the area of the blood vessel to be occluded, as recited in amended claim 1. As described

above, Guglielmi occludes blood flow through electrothrombosis. In order for electrothrombosis to occur, current must be able to flow from the external voltage source to the electrode (secondary coil 28, stainless steel portion 36, platinum coil 56). If the electrode is detached from the stainless steel coil, current can no longer flow to the electrode and the electrode cannot be positively charged. If the electrode cannot be positively charged, the thrombus cannot be formed. Thus, it would be impossible for Guglielmi to occlude blood flow after the wire body is separated from the catheter and the catheter is removed from the area of the blood vessel to be occluded. Furthermore, it would not be obvious to modify the electrode of Guglielmi to form a thrombus after it is detached from the stainless steel coil since this would change the principle operation of the reference. As discussed above, the principle operation of the electrode (platinum coil, secondary coil), and indeed the entire device taught by Guglielmi, is to occlude an aneurysm by creating a thrombus using electrothrombosis. See MPEP § 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

Consequently, for at least these reasons, claim 1, and any claim that depends on claim 1 is allowable, and the Examiner may withdraw the rejection.

## **V. The Proposed Combination Does Not Render Claim 19 Unpatentable**

Independent claim 19 was rejected as being unpatentable over Guglielmi in view of Kupiecki. As amended, claim 19 recites with underlining for emphasis:

abutting a first wall portion of said aneurysm with said front end of said wire body, thereby column loading said wire body and frictionally locking said front end against said first wall portion;

continuing to mechanically push said wire body out of said distal opening of said catheter, thereby curving said section of

said wire body toward a second wall portion of said aneurysm, wherein said section frictionally locks against said second wall portion when said section is column loaded between said first and second wall portions due to said wire body being mechanically pushed forward, thereby forming a portion of said wire body crossing said aneurysm and frictionally locked to said first wall portion and said second wall portion due to said column loading;

repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said aneurysm and frictionally locks against wall portions of said aneurysm when said section is column loaded between said wall portions due to said wire body being mechanically pushed forward, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints ;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said aneurysm with said wire body having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body is physically separated from said catheter and said catheter is removed from said aneurysm; and

forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and said catheter is removed from said aneurysm.

The combination of Guglielmi and Kupiecki as contemplated by the Examiner fails to teach or suggest at least these elements. As discussed above in conjunction with claim 1, Guglielmi fails to teach occluding blood flow in an aneurysm using a wire body that is frictionally locked between first and second wall portions of an aneurysm by column loading, as recited in amended claim 19. Guglielmi also fails to teach or suggest occluding blood flow using the section of the wire body frictionally locked between the first and second wall portions of the aneurysm. Furthermore, Guglielmi does not teach or suggest occluding blood flow and forming a thrombus after the wire body is separated from the catheter and the catheter is removed from the aneurysm.

Guglielmi also fails to teach or suggest occluding blood flow using a wire body section that repeatedly crosses and frictionally locks against wall portions of the aneurysm when the section is column loaded between the wall portions.

Moreover, Kupiecki also fails to teach or suggest at least these elements. Consequently, for at least these reasons, the combinations of Guglielmi and Kupiecki as contemplated by the Examiner do not render claim 19, or any claim that depends from claim 19 unpatentable, and the Examiner may withdraw the rejection.

#### **VI. The Proposed Combination Does Not Render Claim 20 Unpatentable**

Independent claim 20 was rejected as being unpatentable over Guglielmi in view of Kupiecki. As amended, claim 20 recites with underlining for emphasis:

continuing to mechanically push said wire body out of said distal opening of said catheter thereby column loading said section as said wire body is mechanically pushed and curving said section of said wire body toward a second wall portion of said blood vessel lumen, wherein said section frictionally locks against said second wall portion due to said column loading of said section, thereby forming a portion of said wire body crossing said blood vessel lumen and frictionally locked to said first wall portion and said second wall portion;

repeating said continuing step until said section of said wire body has assumed a complexly curved shape, whereby said section repeatedly crosses said blood vessel lumen and frictionally locks against wall portions of said blood vessel lumen due to said column loading of said section, said section thereby forming curvatures in said complexly curved shape which vary continuously without breakpoints;

physically separating said wire body from said catheter by pushing an entirety of said wire body out of said distal opening of said catheter;

occluding blood flow in said blood vessel lumen to be occluded using said wire body having a complexly curved shape that is frictionally locked between said wall portions, wherein said blood flow is occluded after said wire body is physically



separated from said catheter and said catheter is removed from said blood vessel lumen to be occluded; and  
forming a thrombus at a location of said wire body after said wire body is physically separated from said catheter and said catheter is removed from said blood vessel lumen to be occluded.

The combination of Guglielmi and Kupiecki as contemplated by the Examiner fails to teach or suggest at least these elements. As discussed above in conjunction with claim 1, Guglielmi fails to teach occluding blood flow in a blood vessel lumen using a wire body that is frictionally locked between first and second wall portions of the blood vessel by column loading, as recited in amended claim 19. Guglielmi also fails to teach or suggest occluding blood flow using the section of the wire body frictionally locked between the first and second wall portions of the blood vessel. Furthermore, Guglielmi does not teach or suggest occluding blood flow and forming a thrombus after the wire body is separated from the catheter and the catheter is removed from the area of the blood vessel lumen to be occluded.

As discussed above in conjunction with claim 19, Guglielmi also fails to teach or suggest occluding blood flow using a wire body section that repeatedly crosses and frictionally locks against wall portions of the aneurysm when the section is column loaded between the wall portions.

Moreover, Kupiecki also fails to teach or suggest at least these elements. Consequently, for at least these reasons, the combinations of Guglielmi and Kupiecki as contemplated by the Examiner do not render claim 20, or any claim that depends from claim 20 unpatentable, and the Examiner may withdraw the rejection.

**V. Conclusion**

Applicants submit that the claims, as amended, patentably distinguish over the art of record. Applicants earnestly request expedited consideration and allowance of this application.

Respectfully submitted,

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